OCT 0 8 2008

K082761

GE Healthcare

3000 N. Grandview Blvd.
Waukesha, WI 53188

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

This 510(k) summary of Safety and Effectiveness information is submitted in accordance with the requirement of 21 CFR Part 807.87(h).

Date Prepared: September 12, 2008

Submitter:
GE Medical Systems, LLC (GE Healthcare)
3000 N. Grandview Blvd., W-1140
Waukesha, WI 53188

Primary Contact:
Tracey Ortiz
Regulatory Affairs Leader
GE Healthcare
Tel: 262-544-3601, Fax: 262-918-1609
e-mail: tracey.ortiz@ge.com

Secondary Contact:
John Jaeckle
Regulatory Affairs Manager
GE Healthcare
Tel: 262-312-7358, Fax: 262-312-7369
e-mail: john.jaeckle@ge.com

DEVICE IDENTIFICATION

Trade Name: GE LightSpeed 7.2 CT Scanner System

Common/Usual Name: LightSpeed VCT, LightSpeed VCT XT

Classification Name: Computed Tomography X-ray System per 21CFR892.1750

Product Code: 90-JAK

Predicate Device(s): LightSpeed 7.1 CT Scanner System (K061817)
LightSpeed 7.0 CT Scanner System (K040372)

Manufacturer(s):

GE Medical Systems, LLC (GE Healthcare)
3000 N. Grandview Blvd.
Waukesha, WI 53188

GE Yokogawa Medical Systems, LTD.
7-127, Asahigaoka 4 Chome
Hino-Shi, Tokyo, 191-8503 Japan

Distributor: Same as Manufacturer

Marketed Devices: The LightSpeed 7.2 CT Scanner System is of comparable type and substantially equivalent to GE's currently marketed Computed Tomography X-ray Systems that comply with the same or equivalent standards and have similar intended uses, such as the previous LightSpeed CT Scanners.

DEVICE DESCRIPTION

The GE LightSpeed 7.2 CT Scanner System is composed of a gantry, patient table, operator console, computer, and PDU and includes image acquisition hardware, image acquisition and reconstruction software, associated accessories and connections/interfaces to accessories. It is an evolutionary modification to the LightSpeed 7.1 (K061817). It is developed from the hardware platform of the 64 slice LightSpeed 7.1 system by adding new application features that involve changes in hardware, software, firmware, recon, and scan mode.

The GE LightSpeed 7.2 CT Scanner System is designed to be a head and whole body CT scanner incorporating the same basic fundamental operating principles and similar Indications for Use. Materials and construction are equivalent to our existing marketed products, which are compliant with UL 60601-1, IEC 60601-1 and associated collateral and particular standards, and 21CFR Subchapter J.

INDICATIONS FOR USE

The GE LightSpeed 7.2 Computed Tomography X-ray system is intended to produce cross-sectional images of the body by computer reconstruction of x-ray transmission data taken at different angles and planes, including Axial, Cine, Helical (Volumetric), Cardiac, and Gated acquisitions. These images may be obtained either with or without contrast. This device may include signal analysis and display equipment, patient and equipment supports, components and accessories.

This device may include data and image processing to produce images in a variety of trans-axial and reformatted planes. Further the images can be post processed to produce additional imaging planes or analysis results.

The GE LightSpeed 7.2 CT Scanner System is indicated for head, whole body, cardiac and vascular X-ray Computed Tomography applications in patients of all ages.

The device output is a valuable medical tool for the diagnosis of disease, trauma, or abnormality and for planning, guiding, and monitoring therapy.

COMPARISON WITH PREDICATE

The GE LightSpeed 7.2 CT Scanner System is developed from the hardware platform of the 64 slice LightSpeed 7.1 system (K061817). The GE LightSpeed 7.2 CT Scanner System involves changes from the LightSpeed 7.1 system to add new application features that involve changes in hardware, applications software, firmware, recon, and scan mode. The GE LightSpeed 7.2 CT Scanner System uses virtually the same materials, identical operating principles, and has similar indications for use as our existing marketed product, LightSpeed 7.1. We believe the GE LightSpeed 7.2 CT Scanner System is of comparable type and substantially equivalent to our currently marketed systems listed above, complies with the same or equivalent standards, and has the same intended uses.

The LightSpeed 7.2 CT Scanner System will be certified to comply with the X-ray requirements of 21CFR1020.30 and1020.33, as well as the safety requirements of UL 60601-1, and IEC 60601-1 and associated collateral and particular standards.

ADVERSE EFFECTS ON HEALTH

Potential electrical, mechanical and radiation hazards are identified in a risk management summary (hazard analysis) and controlled by:

- System verification and validation to ensure performance to specifications, Federal Regulations, and user requirements.
- Adherence and certification to industry and international standards. (UL/CSA and IEC).
- Compliance to applicable CDRH 21CFR subchapter J requirements.

The device is designed and manufactured under the Quality System Regulations of 21CFR820.

CONCLUSION

The GE LightSpeed 7.2 CT Scanner System is an evolutionary modification to the 64 slice LightSpeed 7.1 system (K061817). It does not result in any new potential safety risks and performs as well as or better than devices currently on the market. The GE LightSpeed 7.2 CT Scanner system will be certified to comply with the X-ray requirements of 21CFR 1020.30 and 1020.33, as well as the safety requirements of UL 60601-1, and IEC 60601-1 and associated collateral and particular standards. GE Healthcare considers the GE LightSpeed 7.2 CT Scanner Systems to be as safe, as effective, and to have substantially equivalent performance to the predicate devices(s).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 0 8 2008

GE Medical Systems, LLC
% Mr. Daniel W. Lehtonen
Responsible Third Party Official
Intertek Testing Services
2307 E. Aurora Rd., Unit B7
TWINSBURG OH 44087

Re: K082761
Trade/Device Name: GE LightSpeed 7.2 CT Scanner System
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: II
Product Code: JAK
Dated: September 19, 2008
Received: September 22, 2008

Dear Mr. Lehtonen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxx	(Gastroenterology/Renal/Urology	240-276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 894.xxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometrics' (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Joyce M. Whang, Ph.D.
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

STATEMENT OF INDICATIONS FOR USE

510(k) Number (if known): K082761

Device Name: **GE LightSpeed 7.2 CT Scanner System**

Indications for Use:

The GE LightSpeed 7.2 Computed Tomography X-ray system is intended to produce cross-sectional images of the body by computer reconstruction of x-ray transmission data taken at different angles and planes, including Axial, Cine, Helical (Volumetric), Cardiac, and Gated acquisitions. These images may be obtained either with or without contrast. This device may include signal analysis and display equipment, patient and equipment supports, components and accessories.

This device may include data and image processing to produce images in a variety of trans-axial and reformatted planes. Further the images can be post processed to produce additional imaging planes or analysis results.

The GE LightSpeed 7.2 CT Scanner System is indicated for head, whole body, cardiac and vascular X-ray Computed Tomography applications in patients of all ages.

The device output is a valuable medical tool for the diagnosis of disease, trauma, or abnormality and for planning, guiding, and monitoring therapy.

Prescription Use_X___ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use_ _ (Part 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K082761